

REMARKS

The remainder of this Reply is set forth under appropriate subheadings for the convenience of the Examiner.

Amendments to the Specification

The specification was amended at page 5, line 13 to correct a typographical in the abbreviation for glomerulonephritis. Support for this amendment is found in the Figure.

The specification was amended at page 8, lines 13 and 15 to correct a typographical error in the designation of oxygen.

The specification was amended at page 17, line 28 to correct a self-evident typographical error in the description of the glomerular filtration rate. Support for this amendment is found in the specification, for example, at page 16, lines 17-20.

Table 1 was amended to correct a typographical error in the abbreviation of Henoch-Schonlein Purpura. Support for this amendment is found in Table 1, line 39.

No new matter is added. Entry is respectfully requested.

Amendments to the Claims and New Claims

Claim 4 is amended to more clearly define Applicant's claimed invention. Support for the amendments to Claim 4 and new Claims 5-9 can be found in the specification. For example, page 6, lines 15-16, describes a progressive kidney disease, as a kidney disease treated by Applicant's claimed method thereby providing support for the amendment to Claim 4. Page 31, lines 6-9, describe primary and secondary glomerulonephritis diseases, thereby providing support for new Claims 5 and 6. Support for new Claim 7 can be found at Table 1, page 37, line 41, which describes ischemic nephropathy. Page 9, lines 12-17, describes measurement of catalytic iron content prior to the onset of clinical symptoms and after onset of clinical symptoms of a kidney, thereby providing support for new Claims 8 and 9.

The amendments to Claim 4 and new Claims 5-9 do not add new matter. Entry is requested.

Applicant's Claimed Invention

Applicant's invention, as set forth in Claims 1-9, is directed to a method for diagnosing a kidney disease in a human, comprising the step of measuring catalytic iron in a urine sample from the human. In one embodiment, the kidney disease is a progressive kidney disease. In another embodiment, the diagnosis is performed prior to onset of clinical symptoms of kidney disease. In yet another embodiment, the diagnosis is performed after the onset of clinical symptoms of kidney disease.

Advantages of Applicant's Claimed Invention

As discussed on pages 1 and 6-9 of the specification, kidney disease generally refers to a disorder of at least one kidney in a human that compromises the function of the kidney. Progressive kidney disease leads to loss of renal function. Current diagnostic methods for kidney diseases include monitoring urine for elevated protein levels, which can occur after significant damage to the kidney, and conducting renal biopsies.

An advantage of Applicant's claimed invention is the diagnosis of a kidney disease with a non-invasive procedure before the onset of clinical symptoms of kidney disease and before significant damage to the kidney has occurred.

Rejection of Claim 1 Under 35 U.S.C. §112, First Paragraph

Claim 1 is rejected under 35 U.S.C. §112, first paragraph for failing to satisfy the enablement requirement. The Examiner stated that while the specification is enabling for a method for diagnosing a kidney disease in a human, wherein the urine sample is obtained from a human having a kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis, the method does not enable any person in the art for a method of diagnosing any and/or all kidney diseases in a human comprising the step of measuring catalytic iron in a urine sample from the human. The Examiner further stated that Applicant's specification failed to provide guidance or working examples, that the art is silent regarding the efficacy of Applicant's method and, therefore, Applicant's claimed method is unpredictable. The Examiner concluded that it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claim.

The specification, at page 5, lines 11-14, and the accompanying Figure, describe increased catalytic iron content in the urine of humans with diabetic microalbuminuria, diabetic proteinuria, glomerulonephritis and ischemic nephropathy. Furthermore, Table 1, on page 37, and Table 2, on page 38 describe increased catalytic iron in the urine of humans having membranous nephropathy, systemic lupus erythematosus, focal segmental glomerulosclerosis, Henoch-Schonlein Purpura, hemolytic uremic syndrome, membranoproliferative glomerulonephritis, chronic glomerulonephritis, ischemic nephropathy, diabetic nephropathy, microalbuminuria and diffuse proliferative glomerulonephritis. Thus, Applicant has provided sufficient guidance and working examples to enable a person skilled in the art to make and use Applicant's claimed invention, as set forth in Claim 1.

The absence of Applicant's claimed invention in the prior art is evidence that Applicant's claimed method is novel and non-obvious, not that it is unpredictable. The wide variety of kidney diseases demonstrated by Applicant in the specification to correlate increased urinary catalytic iron with kidney disease provides guidance to a person skilled in the art to make and use Applicant's claimed method.

The Examiner has presented no evidence that undue experimentation would be required for a person of skill in the art to practice Applicant's claimed invention. Therefore, the specification meets the enablement requirement of 35 U.S.C. §112, first paragraph, as applied to Applicant's claimed invention, as set forth in pending Claim 1.

Rejection of Claims 1-4 Under 35 U.S.C. §112, Second Paragraph

Claims 1-4 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The Examiner stated that Claim 4 has insufficient antecedent basis for the limitation "a progressive kidney disease" and that the metes and bounds of progressive kidney disease have not been delineated.

Claim 4, as amended, is directed to a method for diagnosing a kidney disease that is a progressive kidney disease. Therefore, Claim 4 is clear and meets the requirements of 35 U.S.C. §112, second paragraph.

SUMMARY AND CONCLUSIONS

The specification meets the requirements of 35 U.S.C. §112, first paragraph. Claim 4, as amended, is definite and meets the requirements of 35 U.S.C. §112, second paragraph. Therefore, Applicant respectfully requests reconsideration and allowance of the claims under consideration.

If the Examiner feels that a telephone conference would expedite prosecution of this application, he is invited to call Applicant's undersigned Attorney.

Respectfully submitted,

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